DEC 2 8 2012

Section 5. 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K121397

1. Sponsor/Applicant Name and Address

Company Name: Address:	Sekisui Diagnostics, LLC 6659 Top Gun Street San Diego, CA 92121
Telephone:	858-777-2633
Contact Person:	Mark Stavro Director, Regulatory Affairs
Date Summary Prepared:	05/07/2012

2. Device Name and Classification

Trade Name:	OSOM® iFOB Test OSOM® iFOBT Control Kit
Classification of Device:	21 CFR 864.6550; Occult blood test
Product Code:	KHE
Classification:	Class II

3. Predicate Device

K021423 – Alfa Scientific Designs' Instant-View Fecal Occult Blood Rapid Test (Currently marketed as Quidel QuickVue iFOB Test).

4. Device Description

The OSOM iFOB (Immunochemical Fecal Occult Blood) Test is a rapid test which can detect the presence of occult blood in human fecal samples by detecting the presence of human hemoglobin (hHb). The OSOM iFOB Test is a qualitative assay that employs immuochromatographic, lateral flow technology. A test kit contains 25 pouched Test Devices, 25 Extraction Reagent vials, 25 conjugate vial tips, and 25 sample collection packs. Tests and Reagents are also available in a 50-test kit without sample collection packs, and sample collection packs are available separately in a package of 50. Negative and positive external controls are provided separately as the OSOM iFOBT Control Kit.

The fecal sample collected using an OSOM iFOB sample collection card is placed into a prefilled vial containing Extraction Buffer. This test solution is then dispensed, through a dropper tip containing human hemoglobin antibody conjugated to latex, into the sample well of the Test Device. The sample migrates across the membrane containing a Test line coated with anti-human hemoglobin antibody and a Control line. If hemoglobin is present at or above the level of detection of the test, an antigen/antibody complex will be formed. The appearance of a visible blue Test line and a red Control line in the result window indicates the presence of human hemoglobin in the sample. A red control line must appear for the results to be valid. If a detectable level of hemoglobin is not present, only the red control line will appear. An invalid test occurs when no control line appears.

The control line serves as an internal procedural control, indicating that the test system is functioning correctly and that the operator added a sufficient volume of sample. In addition to the internal control in each Test Device, external controls are available in a separate OSOM iFOBT Control Kit. The Negative Control (buffer solution) and the Positive Control (hHb in buffer solution) are run in the iFOB Test in the same manner as an extracted fecal sample.

5. Intended Use

The OSOM iFOB (Immunochemical Fecal Occult Blood) Test is a rapid immunoassay for the qualitative detection of fecal occult blood by laboratories or physicians' offices. It is useful for the detection of human hemoglobin in human fecal samples and is recommended for use as part of routine physical examinations or when lower gastrointestinal disorders are suspected.

6. Comparison to Predicate Device

The Table below provides a summary of the device characteristics for the OSOM iFOB Test and the predicate device.

Table 1: Comparison of Technological Characteristics of Sekisui Diagnostics OSOM iFOB Test with Legally Marketed Device

Device Characteristics	OSOM iFOB Test [New Device]	Alfa Instant-View FOB Rapid Test [Predicate/ K021423]
Intended Use	A rapid immunoassay for the qualitative detection of fecal occult blood by laboratories or physicians' offices. It is useful for the detection of human hemoglobin in human fecal samples and is recommended for use as part of routine physical examinations or when lower gastrointestinal disorders are suspected.	An immunochemical device intended for the qualitative detection of Fecal Occult Blood by laboratories or physicians' offices. It is useful in determining gastrointestinal (GI) bleeding found in a number of GI disorders, such as diverticulitis, colitis, polyps, and colorectal cancer. Recommended for use in routine physical examinations, hospital monitoring for bleeding patients, and screening for colorectal cancer or GI bleeding from any source.
Specifically detecting:	Qualitative Human hemoglobin (hHb)	Qualitative Human hemoglobin
Specimen	Human fecal specimen	Human fecal specimen
Detection Level	50 ng hHb/mL	50 ng hHb/mL
Assay Method	Immunochromatographic membrane assay	Immunochromatographic membrane assay
Result Format	Negative: Visible red Control line	Negative: Single visible burgundy line

	Positive: Visible red Control line and visible blue Test line	Positive: 2 visible burgundy lines
Antibodies	Capture: Goat polyclonal anti-hHb Detection: Monoclonal mouse anti-hHb conjugated to blue latex	Capture: Anti-hHb antibodies Detection: Monoclonal mouse anti-hHb conjugated to colloidal gold
Internal Control	Visible red Control line	Visible burgundy line
External Controls	Negative: Buffer solution Positive: hHb in buffer solution Provided separately	Negative: Buffer solution Positive: hHb in buffer solution Provided separately
Sample Collection and Transport	Provided applicator stick is used to collect a small portion of feces and apply to sample collection card. Dry card is transported in mailing envelope	Provided grooved sample collection probe is used to collect fecal sample, which is inserted in buffer tube. Buffer tube is transported in mailing envelope
Time to Result	5 minutes	5-10 minutes

7. Summary of Performance Data

Reproducibility and Detection Limit

To demonstrate the reproducibility and limit of detection of the OSOM iFOB Test, an evaluation was conducted at three external physician office (POL) sites and one internal site using three lots of OSOM iFOB Test. Each site tested randomly coded panels of fecal samples spiked with human blood with known concentrations of hemoglobin A at five different concentrations: 0, 37.5, 50, 62.5, and 2000 ng/mL. Each panel consisted of 15 test samples, 3 of each of the 5 hemoglobin concentration levels, dried onto an OSOM iFOB sample collection card.

Testing was performed at the external POL sites by 3 intended users per site, with varying levels of education and work experience. Testing at Sekisui Diagnostics, the reference site, was performed by two experience laboratory professionals. Each POL operator tested, in a random fashion, 1 panel on each of the 3 lots of the OSOM iFOB Test. The Sekisui site tested the same number of samples as the 3 external sites, but the testing was divided between two operators. Testing was

performed on three non-consecutive days, and all operators were blinded to the test sample analyte levels.

The detection level of the OSOM iFOB Test is 50 ng/mL, so the 0 and 37.5 ng/mL hemoglobin levels are expected to have negative results and the 50, 62.5, and 2000 ng/mL levels are expected to have positive results. Test results are summarized in Table 2.

Table 2: OSOM iFOB Reproducibility

	Expected		
OSOM	Positive	Negative	Total
Positive	320	3	323
Negative	5	214	219
Total	325	217	542

The results obtained by the three POL sites and the reference laboratory had an overall agreement of 98.5% (95% CI: 97.4% - 99.0%) to the expected results, with positive percent agreement of 98.5% (95% CI: 96.4% - 99.3%), and a negative percent agreement of 98.6% (95% CI: 96.0 – 99.5%).

The study confirmed the detection level of 50 ng/mL and demonstrated that the OSOM iFOB test produces reproducible results when tested by multiple intended users at multiple sites, on multiple days, over multiple reagent lots.

Sensitivity to Hemoglobin Variants

Human hemoglobin S (hHBS) samples and human hemoglobin C (hHbC) samples were prepared at 50, 100, and 2,000 ng/mL Hb and tested with three lots of OSOM iFOB Test. Results of the testing were all positive, indicating that OSOM iFOB Test detects the presence of HbS and HbC at concentrations of 50 ng/mL and higher.

Hook Effect

Samples with elevated levels of hHbA (2,000 ng/mL), hHbS (2,000 ng/mL), and hHbC (2,000 ng/mL) were prepared and tested with three lots of OSOM iFOB

reagents. Results for all samples were positive, demonstrating that there is no hook (prozone) effect at a hemoglobin level of 2,000 ng/mL.

Performance Compared to a Commercially Available Device

A method comparison study was performed to compare the performance of OSOM iFOB Test to a commercially available predicate device, Alfa Instant-View FOB Rapid Test (K021423), currently marketed as Quidel's QuickVue iFOB Test. Fecal samples were spiked with human blood with known concentrations of hemoglobin A at five different concentrations: 0, 37.5, 50, 62.5, and 2,000 ng/mL. Samples were applied to OSOM iFOB sample collection cards, dried, and tested with the OSOM iFOB Test. Samples for QuickVue testing were transferred to the provided collection tube according to the QuickVue instructions and tested with the QuickVue iFOB Test. Twenty-five replicates of each hemoglobin concentration were tested with each test.

Overall results of the OSOM iFOB Test were compared directly against the QuickVue Test results. A summary of the comparison is provided in Table 3.

Table 3: Comparison of OSOM to QuickVue

	QuickVue		
OSOM	**Positive**	**Negative**	**Total**
Positive	75	1	76
Negative	0	49	49
Total	75	50	125

Overall agreement of OSOM iFOB with QuickVue was determined to be 99.2% (95% CI: 96.0 – 99.5%). Positive agreement was 100% (95% CI: 95.1 – 100.0%) and negative agreement was 98.0% (95% CI: 89.5 0 99.6%). The Method Comparison study demonstrated that the analytical performance of OSOM iFOB Test is substantially equivalent to that of QuickVue iFOB Test.

Cross-Reactivity

Human myoglobin, various nonhuman hemoglobins and myoglobins or meat extracts were added to fecal extract samples at the levels shown in Table 4 and all samples were tested with the OSOM iFOB Test. All test results were negative, indicating no cross-reactivity with any of the substances tested.

Table 4: Potentially Cross-Reacting Substances

Potential Cross-Reactant	Concentration
Human Mb	500 µg/mL
Sheep Hb	500 µg/mL
Horse Hb	500 µg/mL
Bovine Hb	2,000 µg/mL
Porcine Hb	500 µg/mL
Chicken Hb	500 µg/mL
Rabbit Hb	500 µg/mL
Fish Hb	500 µg/mL
Goat Hb	500 µg/mL
Horse Mb	500 µg/mL
Sheep meat extract	500 µg/mL
Beef meat extract	500 µg/mL
Pig meat extract	500 µg/mL
Chicken meat extract	500 µg/mL
Rabbit meat extract	500 µg/mL
Fish meat extract	500 µg/mL
Goat meat extract	500 µg/mL

Interfering Substances

A study was performed to determine the impact on the OSOM iFOB Test when potentially interfering substances typically found in feces were spiked into fecal extract samples with and without 50 ng/mL hHbA. Each of the potential interferents listed in Table 5 was spiked into a Negative fecal extract sample and a Positive (50 ng/mL Hb) fecal extract sample. All samples were tested with the OSOM iFOB Test. Results are summarized in Table 5. No interference was observed for any of the potentially interfering substances tested.

Table 5: Potentially Interfering Substances		
Potential Interferent	**Negative Sample Results**	**Positive Sample Results**
Horseradish Peroxidase, 20,000 µg/mL	Negative	Positive
Broccoli (aqueous extract)	Negative	Positive
Turnip (aqueous extract)	Negative	Positive
Parsnip (aqueous extract)	Negative	Positive
Cauliflower (aqueous extract)	Negative	Positive
Cantaloupe (aqueous extract)	Negative	Positive
Red radish (aqueous extract)	Negative	Positive
Vitamin C, 0.25 mg/mL	Negative	Positive
Iron, 0.065 mg/mL	Negative	Positive
No interfering substance	Negative	Positive

8. Conclusion

The information presented in this Premarket Notification demonstrates that the performance of the OSOM iFOB Test is substantially equivalent in intended use, technological characteristics, and performance to the predicate device, thereby supporting 510(k) clearance.

Equivalence was demonstrated using manufactured reagents along with quality control materials and human fecal samples with defined levels of human hemoglobin.

The studies in this submission demonstrate the substantial equivalence of the OSOM iFOB Test to products already marketed for the qualitative detection of occult blood in human fecal samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Sekisui Diagnostics, LLC
c/o Mr. Mark Stavro
Director of Regulatory Affairs
6659 Top Gun Street
San Diego, California 92121

DEC 2 8 2012

Re: k121397

Trade/Device Name: OSOM® iFOB Test
OSOM® iFOBT Control Kit

Regulation Number: 21 CFR §864.6550
Regulation Name: Occult blood test
Regulatory Class: II
Product Code: KHE
Dated: November 27, 2012
Received: November 28, 2012

Dear Mr. Stavro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua D. Levin -S

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K121397

Device Name: OSOM iFOBT Control Kit

Indications for Use:

The OSOM iFOBT Control Kit is intended for use in quality control testing with the OSOM iFOB Test.

Prescription Use___X___ AND/OR Over-The Counter Use_____

(per 21 CFR 801.109) (per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety